Notice of Allowability	Application No.	Applicant(s)	
	09/439,311	LEE ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *12/7/2004*.

2. ☒ The allowed claim(s) is/are *1,3,16-24,28*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☒ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *2/16/2005* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Joseph K. Hemby, Jr, Registration Number 42,652 on February 16, 2005.

The application has been amended as follows: Authorization was given to cancel claims 2, 8-15 and 26.

Claim 1 (Currently amended): An isolated and purified polynucleotide sequence that is a portion of the flaA coding region of Campylobacter, said polynucleotide sequence consisting of nucleotides 1 – 999 of the DNA SEQ ID NO:1, and said polynucleotide encoding an immunogenic polypeptide.

Claim 2 (Canceled): A recombinant FlaA polypeptide consisting of all or a portion of amino acid sequence SEQ ID NO:2.

Claim 3 (Currently amended): An isolated and purified DNA sequence encoding an immunogenic polypeptide consisting of amino acid residues 1-333 of amino acid sequence of SEQ ID NO:2.

Claim 4 (Canceled): An expression system consisting of an expression vector wherein the polypeptide of Claim 1 is inserted.

Claim 5 (Canceled): The expression system of Claim 4 wherein the expression vector is selected from the group consisting of plasmid and viral and E.coli expression vectors.

Claim 6 (Canceled): An expression system of Claim 5 wherein the plasmid vector is selected from the group consisting of pMal-c2, pMal-p2 and pET.

Claim 7 (Canceled): An expression system of Claim 4 wherein the viral expression vector of Claim 5 is selected from the group consisting of adenovirus, M13, herpesvirus, vaccinia virus and baculovirus.

Claim 8 (Canceled): A method for inducing an immune response to FlaA comprising administering the polypeptide of Claim 2 to a subject.

Claim 9 (Canceled): The method of Claim 8 wherein the polypeptide is administered in conjunction with other known vaccines to form a multivalent formulation.

Claim 10 (Canceled): The method of Claim 8 wherein the polypeptide is administered as an injectable formulation.

Claim 11 (Canceled): The method of Claim 8 wherein the polypeptide is administered as an intranasal formulation.

Claim 12 (Canceled): The method of Claim 8 wherein the polypeptide is administered as an oral formulation.

Claim 13 (Canceled): The method of Claim 8 wherein administering the polypeptide to subjects has no or reduced ability to induce GBS.

Claim 14 (Canceled): A method of reducing campylobacter intestinal colonization in a subject, said method comprising administering an immunogenically effective amount of MBP-FlaA with or without an adjuvant.

Claim 15 (Canceled): A method of reducing campylobacter intestinal colonization in a subject, said method comprising administering an immunogenically effective amount of MBP-FlaA + LT_{R192G}.

Claim 16 (Currently amended) A recombinant expression vector comprising the polynucleotide of Claim 1, wherein said vector comprises said polynucleotide operatively linked for expression in an expression system, wherein said expression vector is selected from the group consisting of plasmid and viral expression vectors.

Claim 17 (Currently amended): A recombinant expression vector system comprising the recombinant expression vector of Claim 16, wherein said expression vector further comprises an E. coli gene encoding maltose binding protein, said polynucleotide sequence being fused to said E.coli gene.

Claim 18 (Currently amended) A composition comprising:

an isolated and purified polynucleotide sequence consisting of nucleotides 1- 999 of SEQ ID NO. 1 encoding an immunogenic polypeptide consisting of amino acid residues 1 - 333 of SEQ ID NO. 2,

wherein said polynucleotide is operatively linked to an expression system selected from the group consisting of plasmid and viral expression vectors and

wherein said expression system is capable of being expressed in competent bacterial cells selected from the group consisting of *E. coli, Shigella* and *Salmonella*.

Claim 19 (Currently amended): The composition of Claim 18, wherein said expression system further comprises an E. coli gene encoding maltose binding protein, said polynucleotide sequence being fused and operatively linked to said E.coli gene.

Claim 20 (Previously presented): The composition of Claim 19, further comprising an adjuvant.

Claim 21 (Previously presented): The composition of Claim 20, wherein said adjuvant is a non-toxigenic form of heat labile E. coli enterotoxin.

Claim 22 (Currently amended) A bivalent immunogenic composition comprising a live, attenuated, carrier strain of bacteria, wherein said bacteria is transformed with either a plasmid or viral expression vector system operatively linked to an isolated and purified polynucleotide sequence that is a portion of the flaA coding region of Campylobacter, said polynucleotide sequence consisting of nucleotides 1 - 999 of the DNA SEQ ID NO:1, said polynucleotide encoding an immunogenic polypeptide consisting of amino acid residues 1-333 of SEQ ID NO 2.

Claim 23 (Currently amended): The bivalent immunogenic composition of Claim 22, wherein said expression system further comprises an E. coli gene encoding maltose binding protein, said polynucleotide sequence being fused to said E. coli gene and said E.coli gene being contained in said expression vector system.

Claim 24 (Previously presented): The bivalent immunogenic composition of Claim 22, wherein said carrier strain comprises Salmonella or Shigella.

Claim 25 (Canceled): The polynucleotide sequence of Claim 1 encoding said immunogenic polypeptide that has reduced or no induction of Guillain-Barre Syndrome.

Claim 26 (Canceled): The immunogenic polypeptide of Claim 3 that has reduced or no induction of Guillain-Barre Syndrome.

Claim 27 (Canceled): The isolated and purified polynucleotide sequence of Claim 16, wherein said sequence is useful in reducing colonization of Camplyobacter.

Claim 28 (Currently amended): The composition of claim 18 wherein said polypeptide is capable of reducing colonization of Campylobacter when administered as a vaccine.

Reasons for allowance

2. The following is an examiner's statement of reasons for allowance:

The instantly claimed isolated and purified polynucleotide encodes an immunogenic polypeptide, wherein the polypeptide upon administration to an immunocompetent host induces a protective immune response. The specific portion of the flaA coding sequence that encodes the peptide sequence that functions as a vaccine composition was neither taught nor reasonable suggested in the prior art of record. The instantly claimed species of invention defines over the prior art of record, and is a novel and non-obvious species of polynucleotide; the claims are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
February 18, 2005

L. R. F. Smith

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